REMARKS

In the Office Action dated December 14, 2006, the Examiner has withdrawn the Restriction Requirement mailed on August 22, 2006, and has examined claims 1-30. Claims 5 and 7-22 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1 and 5-20 of U.S. Patent No. 6,699,691. Claims 1-22 are rejected under 35 U.S.C. §112, second paragraph, as indefinite. Claims 26-30 are rejected as constituting new matter and failing to comply with the written description requirement under 35 U.S.C. §112, first paragraph. Claims 1-22 are also rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 1-22 are further rejected under 35 U.S.C. §102(b) as anticipated by Sears et al., *Yeast*, 14: 783-790 (1998), as evidenced by GenBank Accession No. AF027961. Claims 1-22 and 24 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Stroman et al. (U.S. Patent No. 4,855,2231), as evidenced by GenBank Accession No. 102097. Claims 1-20, 24 and 25 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Buckholz (EP 0244598). Claims 26-29 rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Buckholz (EP 0244598) in view of Romanos et al., *Yeast* 8: 423-488 (1992). Claim 23 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

In the first instance, Applicants observe that claim 23 is an independent claim, rather than a claim dependent upon a rejected base claim as the Examiner has indicated. Therefore, it is

believed that claim 23 is allowable in its present form.

Applicants have also canceled claims 1-22 and 24-30 without prejudice, and have added claims 31-55 to further delineate certain preferred embodiments of the present invention.

Specifically, new claims 31-35 are directed to isolated polynucleotides "consisting of" SEQ ID NOS: 16-19 and 21, respectively.

New claim 36 is directed to an isolated polynucleotide comprising SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, one to three copies of SEQ ID NO: 20, and SEQ ID NO: 21, wherein said nucleic acid does not contain SEQ ID NO: 19. Combinations of the regulatory elements of SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 20, and SEQ ID NO: 21, without SEQ ID NO: 19, are supported by the specification, for example, on page 25, lines 5 and 26-27, and page 26, line 1. The recitation of "one to three copies of SEQ ID NO: 20" is supported by the specification on page 25, line 27.

New claim 37 is directed to an isolated polynucleotide comprising SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 20, and SEQ ID NO: 21, wherein said nucleic acid does not contain SEQ ID NO: 19. Combinations of the regulatory elements of SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 20, and SEQ ID NO: 21, without SEQ ID NO: 19, are supported by the specification on page 26, lines 1-3.

Dependent claims 38-55 are directed to vectors, host cells and methods of producing a protein, and are supported by the specification and previously presented claims.

It is respectfully submitted that the foregoing amendments do not introduce new matter. It is further respectfully submitted that all of the rejections are overcome in view of the cancellation of the rejected claims and in view of the following remarks relating to the newly presented claims.

Specifically, with respect to the non-statutory obviousness-type double patenting rejection, claim 1 of U.S. Patent No. 6,699,691 is directed to an isolated polynucleotide consisting of the nucleotide sequence as set forth in SEQ ID NO: 20. The polynucleotide, as presently claimed, is characterized by one of SEQ ID NOS: 16-19 and 21, or by a combination of several regulatory elements. Therefore, the presently claimed polynucleotide and the related vectors, host cells and methods, are patentably distinct from the claimed subject matter of U.S. Patent No. 6,699,691. As such, the non-statutory obviousness-type double patenting rejection is overcome, and withdrawal thereof is respectfully requested.

Regarding the rejection under 35 U.S.C. §112, second paragraph, the Examiner contends that the language, "under conditions of high stringency", renders the claims vague.

Additionally, in raising the written description rejection under 35 U.S.C. §112, first paragraph, the Examiner contends that the specification fails to provide adequate support for regulatory regions that encompass polynucleotides that hybridize under "high stringency" conditions to a specified sequence or that have at least 80% sequence homology to a fragment or the full-length molecule of a specified sequence.

It is respectfully submitted that the claims currently presented do not include any hybridization or sequence homology language. Accordingly, Applicants respectfully submit that the rejections under 35 U.S.C. §112, first and second paragraphs, are overcome, and withdrawal thereof is respectfully requested.

With respect to the new matter rejection, as discussed above, new claims 31-55 are fully supported by the specification. Withdrawal of the rejection is therefore respectfully requested.

With respect to the prior art rejections, the Examiner has cited Sears et al. (*Yeast* 14:

783-790, 1998), Stroman et al. (U.S. Patent No. 4,855,2231), and Buckholz (EP 0244598), respectively, as anticipating references under §102.

Applicants respectfully submit that none of these references teach a polynucleotide consisting of SEQ ID NO: 16, 17, 18, 19, or 21, as recited in claims 31-35. Further, none of these references teach a polynucleotide comprising a combination of the regulatory elements of SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 20, and SEQ ID NO: 21, each in its entirety, and without SEQ ID NO: 19, as recited in claim 36. Additionally, none of these references teach a polynucleotide comprising a combination of the regulatory elements of SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 20, and SEQ ID NO: 21, each in its entirety, and without SEQ ID NO: 19. Clearly, the claims, as presently recited, are not taught by any of Sears et al., Stroman et al., or Buckholz.

Additionally, the prior art references, including Sears et al., Stroman et al., Buckholz, and Romanos et al. (the secondary reference relied upon by the Examiner in raising the §103 rejection), did not recognize the positive or negative activities conferred by the individual regulatory elements set forth in SEQ ID NOS: 16-21. Therefore, these references would not have provided any motivation or suggestion, or any reason, to those skilled in the art to make the specific combination of regulatory elements, as presently claimed.

Therefore, it is respectfully submitted that the presently presented claims are not anticipated or rendered obvious by the cited references. Withdrawal of all the §102 rejections and the §103 rejection is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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